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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,155	03/01/2004	Arnon Lavie	02-134-D	3822
7590 06/20/2007			EXAMINER ·	
Jason J. Derry McDonnell Boehnen Hulbert & Berghoff LLP			YAO, LEI	
300 S. Wacker I Chicago, IL 606	S. Wacker Drive cago, IL 60606		ART UNIT	PAPER NUMBER
,		•	1642	· -
			VALUE DATE	DEL WERV MODE
			MAIL DATE	DELIVERY MODE
			06/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)			
		10/791,155	LAVIE ET AL.			
Office Action Summary		Examiner	Art Unit			
		Lei Yao, Ph.D.	1642			
	The MAILING DATE of this communication app	i e	ne correspondence address			
Period fo	• •					
WHIC - Exter after - If NO - Failu Any r	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DAnsions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICAT 36(a). In no event, however, may a reply by the state of the	ION. se timely filed from the mailing date of this communication. DNED (35 U.S.C. § 133).			
Status		,				
1)⊠	Responsive to communication(s) filed on 3/37/	<u> 2007</u> .				
2a)⊠	This action is <b>FINAL</b> . 2b) This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11	, 453 O.G. 213.			
Dispositi	on of Claims		·			
5)□ 6)⊠ 7)□	Claim(s) 1,6-8 and 69 is/are pending in the appearance of the above claim(s) is/are withdraw Claim(s) is/are allowed.  Claim(s) 1,6-8 and 69 is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or	vn from consideration.				
Applicati	on Papers					
10)	The specification is objected to by the Examine The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	epted or b) objected to by the drawing(s) be held in abeyance. ion is required if the drawing(s) is	See 37 CFR 1.85(a). objected to. See 37 CFR 1.121(d).			
Priority u	ınder 35 U.S.C. § 119		,			
12) <u> </u>	Acknowledgment is made of a claim for foreign  All b) Some * c) None of:  1. Certified copies of the priority documents  2. Certified copies of the priority documents  3. Copies of the certified copies of the prior  application from the International Bureau  See the attached detailed Office action for a list	s have been received. s have been received in Application in the second	cation No eived in this National Stage			
2) 🔲 Notic 3) 🔲 Inforr	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	4) Interview Summ Paper No(s)/Ma 5) Notice of Inform 6) Other:	il Date			

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## Response to Argument and Amendment

The Amendment filed on 3/27/2007 in response to the previous Non-Final Office Action (12/27/2006) is acknowledged and has been entered.

Claims 2-5, 9-68 and 70-169 have been cancelled. Claims 1, 6-8, and 69 are pending and under consideration.

#### Rejections Withdrawn

- 1. The rejection of 1, 6-8, and 69 under 35 USC § 101 because the claimed invention is not supported by either a specific, substantial, and credibly asserted utility is withdrawn in view of applicant's argument.
- 2. The rejection of claims 1, 6-8 and 69 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of amendment to the claims.

## Response to Arguments

### Rejection under 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6, 8, and 69 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The response filed 3/27/2007 has been carefully considered but is deemed not to be persuasive. Applicant argues that Zhu et al., teach that both nuclear and cytosolic dCK can phosphorylate nucleoside analog AraC (figure 2 and 3) and nucleoside analogs phosphorylated by either nuclear or cytosolic dCK, not mitochondrial dCK (figure 3). In response to this argument, the Office agrees with applicant that the nucleoside analog AraC is phosphorylated by both nuclear and cytosolic dCK, which are <u>transfected</u> and

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expressed inside of the cells. However, the claimed invention is drawn to an antibody-conjugate dCK used for treating leukemia blast cells by the mechanism of phosphorylation of nucleoside analogs incorporated into DNA and causing cell death. As such, the antibody conjugate as treatment agent is required to be penetrated into nucleus in order to perform the function and be used by one skilled in the art for treating a tumor. The specification neither provides a teaching showing the antibody-conjugate works inside of the nucleus of a cell, nor a direction or guideline to show how the antibody conjugate phosphorylate the nucleoside, such as AraC, located inside of the nucleus of the cell. The teaching of Zhu et al., does not resolve the problem or suggest the invention enabled because the transfected dCK-GFP is originally expressed and stayed inside of the nucleus of the cells. In addition, examples and figures such as figures 6-9, do not show the significant difference in the cells treated with Ara C alone or Ara C plus the conjugate. Thus, Applicant's argument has not been found persuasive, and the rejection is maintained.

In addition, based on the applicant's argument, replication of DNA in mitochondria seems not be concerned in this application, therefore, the Office will not further discuss this issue.

#### Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Examiner Art Unit 1642

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